



SLOVENSKI STANDARD
oSIST prEN ISO 22413:2020
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**Pribor za prenos farmacevtskih pripravkov - Zahteve in preskusne metode
(ISO/DIS 22413:2020)**

Transfer sets for pharmaceutical preparations - Requirements and test methods
(ISO/DIS 22413:2020)

Überleitgeräte für pharmazeutische Zubereitungen - Anforderungen und Prüfverfahren
(ISO/DIS 22413:2020)

Ensemble de transfert pour préparations pharmaceutiques - Exigences et méthodes
d'essai (ISO/DIS 22413:2020)

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Transfer sets for pharmaceutical preparations — Requirements and test methods

Ensemble de transfert pour préparations pharmaceutiques — Exigences et méthodes d'essai

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use.

This third edition cancels and replaces the second edition (ISO 22413:2010), which has been technically revised.

The main changes compared to the previous edition are as follows:

- the structure (moving all tests to the new [Annex A](#)) and partly the content were aligned with ISO 8536-4;
- for formal reasons [Clause 3](#) on normative references was inserted;
- in sub-clause [6.6](#) (formerly 5.6) the [Table 1](#) on penetration force was amended by a new entry for a counterpart according ISO 15747;
- [6.7](#) (formerly 5.7) on fragmentation was more clarified;
- the former sub-clause 5.10 on transfer sets with housing was deleted;
- the former Clause 12 on the storage was deleted;
- [Clause 10](#) (formerly Clause 13) on the labelling was completely updated according the current requirements;
- [Clause 11](#) on the disposal has been inserted due to the single-use character of the product;
- the former [Annexes A](#) and B on testing of fragmentation of transfer sets were moved to a new [Annex A](#) on physical tests with appropriate sub-clauses;
- most of the tests in [Annex A](#) were, as far as necessary, aligned with the appropriate tests in ISO 8536-4;
- a new [Clause A.8](#) on a test for stress cracking of small bore connectors was inserted;

— the normative references and the bibliography were updated.

A list of all parts in the ISO 22413 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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ISO/DIS 22413:2020(E)**Introduction**

Transfer sets for pharmaceutical preparations transmit fluids from one container to another. The transfer sets mix fluids or dissolve dry substances and are used in combination with infusion and injection containers.

The transfer sets consist either of two piercing devices or of a piercing device in combination with a small bore connector, which may be connected with each other in different ways. Transfer sets may have a housing.

Examples of different designs:

- a) two piercing devices connected to each other (similar to piercing devices of infusion containers);
- b) a metal cannula, bevelled on both sides or a combination of a) and b);
- c) metal cannulae mostly having a hub or a grip plate in the middle to be fixed to the plastic part;
- d) plastic piercing devices directly connected to a grip plate, or held by a tube at a distance to allow a higher hydrostatic pressure;
- e) piercing devices with an additional ventilation channel that may end in the other tip or outside;
- f) piercing devices also with an air filter;
- g) piercing device in combination with a small bore connector;
- h) piercing device in combination with a small bore connector and a particle filter.

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Transfer sets for pharmaceutical preparations — Requirements and test methods

1 Scope

This document applies to sterilized single use transfer sets that are used for pharmaceutical preparations.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3826-2, *Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets*

ISO 7864:2016, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 8362-2, *Injection containers and accessories — Part 2: Closures for injection vials*

ISO 8536-2, *Infusion equipment for medical use — Part 2: Closures for infusion bottles*

ISO 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15747, *Plastic containers for intravenous injections*

ISO 80369-1, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

ISO/DIS 22413:2020(E)**4 Design and designation****4.1 Design for transfer sets without housing**

The designs of the individual components are given in [Figures 1 to 8](#). The drawings serve as an illustration of possible transfer sets. Other designs are acceptable.

The key for [Figures 1 to 7](#) is to be found on page 3.

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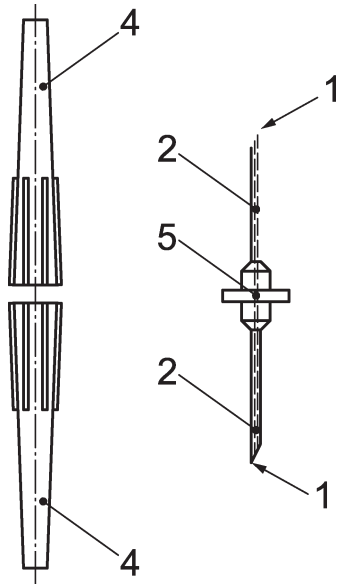


Figure 1 — Transfer set with one channel

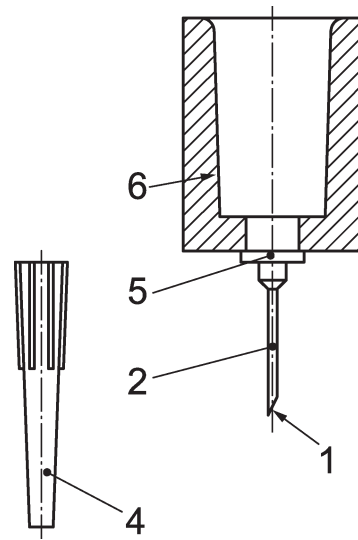


Figure 2 — Transfer set with one channel in combination with a small bore connector

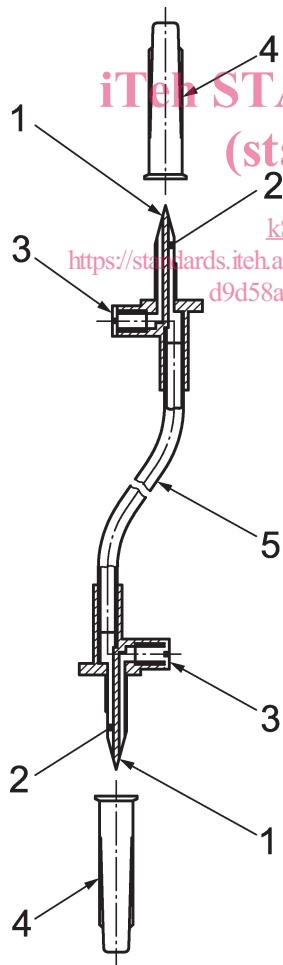


Figure 3 — Transfer set with an air inlet/air outlet

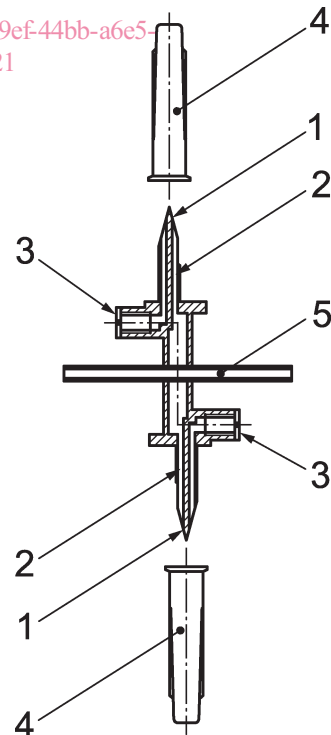


Figure 4 — Alternative transfer set with an air inlet/air outlet

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